# This Page Is Inserted by IFW Operations and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

### IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

## (12) UK Patent Application (19) GB (11) 2 296 868 (13) A

(43) Date of A Publication 17.07.1996

- (21) Application No 9500654.0
- (22) Date of Filing 13.01.1995
- (71) Applicant(s)

  Galai Eihouss

Galai Elhoussein Elsayed Farag 18a Kempston Road, BEDFORD, MK42 9DP, United Kingdom

- (72) Inventor(s)

  Galal Elhoussein Elsayed Farag
- (74) Agent and/or Address for Service
  Galal Elhoussein Elsayed Farag
  18a Kempston Road, BEDFORD, MK42 9DP,
  United Kingdom

- (51) INT CL<sup>6</sup>
  A61B 17/42
- (52) UK CL (Edition O )
  A5R REYE
- (56) Documents Cited EP 0419024 A1 US 5281229 A US 4730617 A
- (58) Field of Search
  UK CL (Edition N ) A5R REYE
  INT CL<sup>6</sup> A61B 17/42 17/44
  Online: WPI

#### (54) Obstetrical rotational vacuum cup

(57) A new vacuum cup, the Rotational Vacuum Cup (RVC) - has been specifically designed for mid-pelvic rotational deliveries and has the advantage of directly effecting rotation of the fetal occiput to an anterior position before actual traction starts. The RVC consists of a metal cup (f) with an eccentrically placed suction nozzle pointing upwards (e). The center of the cup has a cuboid shaped elevated nob (d) that can fit into the lower end of a T-shaped metal handle (b) for rotation. A metal chain (c) attached to the cup nob has been made to pass through the handle for some distance and ends up in a removable metal ring (a) that acts to lock the handle for traction.

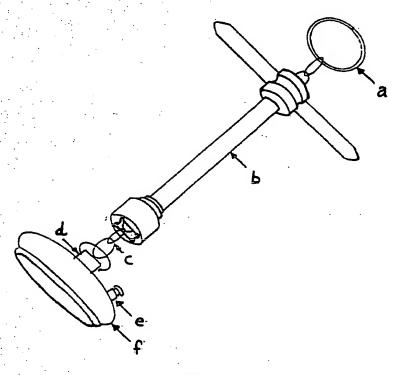


Fig1

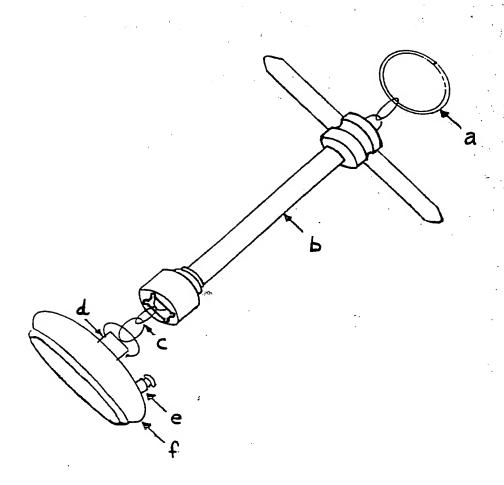
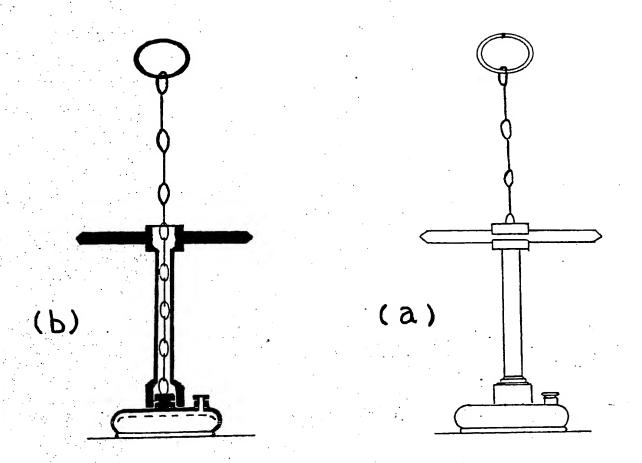


Fig1



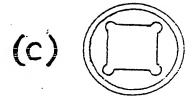
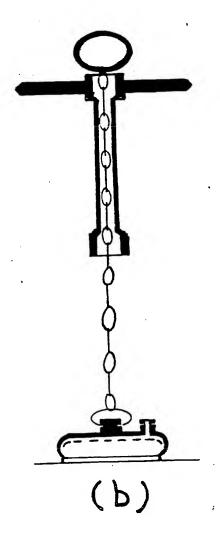


Fig 2



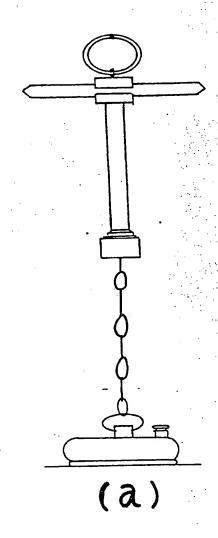


Fig3

#### THE ROTATIONAL VACUUM CUP

This invention relates to a new vacuum cup which can be used for midpelvic rotational ventouse deliveries.

Over the past decade, evidence in favour of the better safety record of the vacuum extractor(VE) rather than the forceps has continued to increase. Recent modifications of vacuum cup design helped reduce the likelihood of delivery failure. Introduction of a new policy that offers a rational approach to the use of the different ventouse cups, for well defined indications is recommended. This is similar to the attidude of introducing special types of forceps for specific obstetric indications. Examples include Piper's forceps for delivery of the aftercoming head in breech presentation and Kielland's forceps for mid -pelvic rotation when correction of asynclitism is required. Doubts regarding the wisdom of continuing to use rotational forceps arise because of their association with serious maternal trauma and poor neonatal outcome, and the use of the VE as an alternative method has been recommended.

A deficiency of the VE is the difficulty of ensuring anterior rotation of the occiput particularly in mid-pelvic operations. Malrotations and attitudes of deflexion of the fetal head presents the greatest difficulty in effecting successful delivery by means of the VE. A good application is not always easy when the occiput is posterior or lateral. In deciding between different cup designs in a given clinical setting, fetal safety is the prime consideration. Using currently available metal cups, rotational deliveries are often difficult and autorotation of the head does not always happen. Strong traction may be required to bring the fetal head down to the pelvic floor and clearly there is danger should reasonable traction be exceeded. Also because the initial pulls may have to be oblique, sideways strain during extraction and cup detachments may occur, adding an increased risk of fetal scalp injury and cephalhaematoma.

According to the present invention there is provided a new ventouse cup which has been specifically designed for mid-pelvic rotational deliveries and may have the advantage of directly effecting rotation of the occiput to an anterior position before actual traction starts.

The Rotational Vacuum Cup (RVC) consists of a bell shaped steel vacuum cup with an eccentrically placed suction nozzle pointing upwards. The center of the cup has a cuboid shaped elevated nob that can fit into the lower end of a T-shaped metal traction handle so that the two pieces can move as one unit when locked together to be used for rotation.

A metal chain attached to the cup nob has been made to pass through the traction handle for some distance and ends up in a removable metal ring that acts to hold the handle when separated from the cup nob to be used for traction. A specific embodiment of the invention will now be described by way of example with reference to the accompaning drawing in which:-

- Figure 1 shows in prespective, the different parts of the RVC with the handle half way along the metal chain.
- Figure 2 (a) shows the handle in position on the cup when used for rotation.
- Figure 2 (b) shows a cross-section of figure 2(a) illustrating how the nob on the top of the cup fits into the lower end of the handle figure 2 (c).
- Figure 3 (a) illustrates the position of the handle during traction and its relation to the cup and the locking metal ring.
- Figure 3 (b) shows a cross-section of figure 3 (a).

Referring to the drawing the RVC comprises a metal cup [Fig.1/f] similar to the other ordinary metal cups and which is 60 mm in diameter (can also be used in a size of 55 mm diameter), and which has an eccentrically placed suction nozzle on the upper side pointing upwards [Fig.1/e].

The center of the cup has a cuboid shaped elevated nob [Fig.1/d] 1.2 cm3. This nob can fit into the lower end [Fig.2/c] of a T-shaped m tal traction handle made of steel [Fig.1/b] and [Fig.2/a & 2/b], so that the two pieces can move as one unit to be used for rotation of the head of the fetus. The traction handle is 14 cm long with the external diameter of the main stem [Fig.1/b] measuring 2 cm.

A metal chain 25 cm in length [Fig.1/b] attached to the cup nob [Fig.1/d] has been made to pass through the traction handle for some distance (11 cm) and ends up in an oval metal ring made of steel [Fig.1/a] and 4-5 cm in diameter, and which is used for locking the handle after its separation from the cup to be used for traction [Fig.3/a & 3/b]. The ring has a 1 mm gap across its thickness so that a spring-like action can be used to remove the ring from the chain and therefore disconnecting the handle for the purpose of sterilizing the instrument.

#### CLAIMS

- A vacuum extractor (ventouse) cup the center of which has a cuboid shaped elevated nob, a T-shaped metal traction handle the lower end of which can fit onto the cup nob, a metal chain attached to the cup nob and which passes through the traction handle, a removable metal ring which can be attached to the end of the chain and locks the traction handle.
- 2 A vacuum extractor cup as claimed in claim 1, wherein two cup sizes can be used 60 mm and 55 mm.
- 3 A vacuum extractor cup as claimed in claims 1 and 2, wherein the cup as designed is specifically used for mid-pelvic rotational deliveries but can also be used as an ordinary ventouse cup to effect other cephalic deliveries without the use of rotation.

Patents Act 1977  Examiner's report to the Comptroller under Section 17  (The Search report)	Application number GB 9500654.0		
Relevant Technical Fields	Search Examiner MR N A FRANKLIN		
(i) UK Cl (Ed.N) A5R (REYE)			
(ii) Int Cl (Ed.6) A61B 17/42, 17/44	Date of completion of Search 4 MAY 1995		
Databases (see below) (i) UK Patent Office collections of GB, EP, WO and US patent specifications.	Documents considered relevant following a search in respect of Claims:- 1-3		
(ii) ONLINE: WPI	1		

#### Categ ries of documents

X:	Document indicating lack of novelty or of inventive step.	P:	Document published on or after the declared priority date but before the filing date of the present application.
Y:	Document indicating lack of inventive step if combined with one or more other documents of the same category.	E:	Patent document published on or after, but with priority date earlier than, the filing date of the present application.
<b>A</b> :	Document indicating technological background and/or state of the art.	<b>&amp;</b> :	Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages			Relevant to claim(s)
A	EP 0419024 A1			
Α	US 5281229	(NEWARD) note Figure 1		
<b>A</b>	US 4730617	(KING0 note Figure 3 & column 5 lines 14-49		
	·	·		
	,			
		;		## ## 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
		-		4.°